K133730

510(k) Summary

as required by 807.92

JAN 3 1 2014

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
Manager
Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Telephone: 81-42-589-8429
Fax: 81-42-589-8053

3. Date of Submission

November 29, 2013

4. Device Trade Name

CO Pilot

5. Common Name

Picture Archiving Communications System

6. Classification, Product Code

Class II, 90LLZ

7. Predicate Device

REGIUS Unitea, 510(k) number K071436
Acies, 510(k) number K101842
Opal-RAD TM, 510(k) number K063337

8. Device Description

The "CO Pilot Software" is intended for installation on REGIUS Unitea (510(K) number: K071436), and provides unit for creating display-use annotation such as line, curve, and character information, unit for measuring the distance between 2 points and angle formed between 3 points and Transfer GUI data to the GUI control module to REGIUS Unitea System Control Program

9. Indications for Use

The CO pilot is intended for installation on an off-the-shelf PC (console of REGIUS Unitea / 510(K) number: K071436) for meeting or exceeding minimum specifications. The CO pilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The CO pilot software can process and display images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and

other DICOM compliant modalities. The CO pilot must not be used for primary image diagnosis in mammography.

10. Substantial Equivalence to Predicate Device

The predicate devices of CO Pilot are Picture Archiving Communications System (K071436, K101842, and K063337).
A comparison of the Indications for Use, Configuration, Specifications, and Principal of Operation of this proposed device and the predicate devices are almost identical or within a scope of substantial equivalent, the materials, the electrical safety (IEC 60601-1) and the electromagnetic compatibility testing (IEC 60601-1-2) won't be issue for this proposed device.

In technological characteristics, Verification and Validation, Risk management based on ISO14971 had been completed without problem, Verification and Validation showed equivalent evaluation outcome with the predicate devices, which has supported a fact that no impacts in technological characteristics such as design, material chemical composition energy sauce and other factors of the proposed device were recognized.

The all evaluation results can assure that there is no safety, effectiveness and performance issue or no differences were found in further than the predicate devices have which has been regally marketed the United States. Therefore, we confirmed that the function quality of proposed device has the substantial equivalency with orthopedic or chiropractic supporting functions quality that predicate devices have. .

11. Conclusion

Comprehensively, we conclude that the CO Pilot has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.

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510(k) Number: **K133730 – Konica Minolta, Inc.**

Digital Signature Concurrence Table	
Reviewer Sign-Off	Yanna Kang January 29, 2014
Branch Chief Sign-Off	Robert Ochs January 29, 2014
Division Sign-Off	Sean M. Boyd -S 2014.01.31 15:34:53 -05'00'

QC: FMEba:fme:1/29/2014

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

Konica Minolta Inc.
% Mr. Russell Munves
STORCH, AMINI & MUNVES, P.C.
140 East 45th Street, 25th Floor
Two Grand Central Tower
NEW YORK NY 10017

Re: K133730
Trade/Device Name: Co Pilot/REGIUS Unitea
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 2, 2013
Received: December 6, 2013

Dear Mr. Munves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K133730

Device Name : CO Pilot

Indications for Use:
The CO pilot is intended for installation on an off-the-shelf PC (REGIUS Unitea / 510(K) number: K071436) meeting or exceeding minimum specifications. The CO pilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The CO pilot software can process and display images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The CO pilot must not be used for primary image diagnosis in mammography.

Prescription Use___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K133730